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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/616,301 | 07/10/2003 | Yoav Kimchy | 25854 | 1622 |

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MARTIN D. MOYNIHAN d/b/a PRTSI, INC.
P.O. BOX 16446
ARLINGTON, VA 22215

| EXAMINER | |
|---|---|
| CHAO, ELMER M | |
| ART UNIT | PAPER NUMBER |
| 3737 | |
| MAIL DATE | DELIVERY MODE |
| 07/15/2009 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/616,301 | KIMCHY ET AL. | |
| | Examiner | Art Unit | |
| | ELMER CHAO | 3737 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *07 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-4 and 6-19* is/are pending in the application.

4a) Of the above claim(s) *9-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-8 and 16-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/4/2009; 4/26/2009; 2/14/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

1. Acknowledgement is made of the amendment filed 4/7/2009.

### *Specification*

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The title must be different from the title of the patented parent case.

### *Information Disclosure Statement*

3. The information disclosure statements (IDS) submitted on 6/4/2009, 4/26/2009, & 2/14/2009 were filed after the mailing date of the non-final office action on 10/7/2008. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

### *Double Patenting*

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. **Claims 1-4, 6, 7, and 16-19** are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9, 60-64, 81, 82, 91, 92, 98, 109-117, and 120-125 of copending Application No. 10/240,239 in view of Houzego et al. (U.S. 6,632,216 B2). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of Application 10/240,239 disclose all of the required limitations except for circuitry to determine location and orientation of the probe. However, Houzego et al. teach a capsule probe with location and orientation tracking (col. 1, lines 40-44). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to include circuitry to detect location and orientation in order to determine the exact location that the image is being obtained (col. 1, lines 40-44).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. **Claims 1 and 16-19** are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 40, 46, 48, 49, 58, 64, and 65 of copending Application No. 11/132,320 in view of Houzego et al. (U.S.

6,632,216 B2). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of Application 11/132,320 disclose at least all of the required limitations except for circuitry to determine location and orientation of the probe. However, Houzego et al. teach a capsule probe with location and orientation tracking (col. 1, lines 40-44). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to include circuitry to detect location and orientation in order to determine the exact location that the image is being obtained (col. 1, lines 40-44).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. **Claims 1-4, 6, 7, and 16** are rejected under 35 U.S.C. 103(a) as being unpatentable over Raylman et al. (U.S. 6,076,009), henceforth referred to as Raylman '009, in view of Raylman et al. (U.S. 6,236,880 B1), henceforth referred to as Raylman '880.

Raylman '009 teach an ingestible device (fig. 2, item 1) for diagnosing body cavities comprising: a probe, operative to acquire, along said gastrointestinal tract (col. 19, lines 35-40), a diagnostic image of nuclear radiation of a radiopharmaceutical (col. 19, lines 40-44); data-handling apparatus, in signal communication with said probe, for receiving and handling imaging data, generated by said probe (fig. 2, item 13); a power source, for powering said probe and data-handling apparatus, and power source within (fig. 4, item 70), wherein said ingestible device comprises a plurality of nuclear-radiation detectors, arranged around said probe (fig. 8 & 9, items 30 & 40; col. 19, lines 40-44), wherein the nuclear radiation detectors are arranged for detecting gamma and beta radiation (col. 3, lines 61-65).

Raylman '009 teach the limitations as discussed above but fail to explicitly teach circuitry with a sensor to determine location and orientation of the ingestible device. However, in the same field of endeavor, Raylman '880 teach determining location and orientation of the tip of the ingestible device (col. 9, lines 62-67, refer to the operator determining the orientation). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to automate the process of determining the location and orientation of the tip of the ingestible device in order to free the operator of the task. Such a modification is considered automating a manual activity (for motivation see In re Venner, 262 F.2d 91, 95, 120 USPQ 193, 194) and can be conducted with surgical tracking systems well-known in the art.

9. **Claim 8** is rejected under 35 U.S.C. 103(a) as being unpatentable over Raylman '009 in view of Raylman '880 as applied to claim 1 above, and further in view of Zhang et al. (Society of Nuclear Medicine, June 2000). Raylman '009 and Raylman '880 teach the limitations as discussed above but fail to explicitly teach an ingestible device arranged as a Compton camera. However, in the same field of endeavor, Zhang teaches a transrectal imaging probe based on Compton camera techniques (No. 68, second sentence). It would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the invention to include a Compton camera probe as evidenced by Zhang. Such a modification would allow the ingestible device to have high sensitivity and high resolution (No. 68, second sentence).

10. **Claims 17-19** are rejected under 35 U.S.C. 103(a) as being unpatentable over Raylman '009 in view of Raylman '880, and further in view of Houzego et al. (U.S. 6,632,216 B2). Raylman '009 and Raylman '880 teach the limitations as discussed above but fail to explicitly teach the ingestible device being shaped and sized as a swallowable pill with orientation and location transmitting capabilities. However, in the same field of endeavor, Houzego et al. teach an ingestible device being shaped and sized as a swallowable pill with orientation and location-tracking capabilities (col. 1, liens 40-44; col. 7, lines 43-49). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to use an ingestible device being shaped and sized as a swallowable pill with orientation and location tracking capabilities

or order to reach a chosen location in the gastrointestinal tract of a mammal (for motivation see col. 1, lines 10-25).

***Response to Arguments***

11. Applicant's arguments filed 4/7/2009 have been fully considered but they are not persuasive.

Regarding Applicants' arguments with respect to claims 1-4 and 6-19, Applicants argue that Raylman '009 does not teach an ingestible device (page 7, paragraphs 4 & 5, Remarks field 4/7/2009). Even though Raylman '009's probe is used while a portion of the probe is outside the body being held by a hand, the other portion of the probe can still be considered ingested if used inside the throat, esophagus, or GI tract. Therefore, the probe can still be considered ingestible. By Applicants claiming "an ingestible device", they do not preclude a device that is partially ingestible. Furthermore, it can be argued that Raylman '009's entire device is ingestible. Just because a device might be used for a certain purpose does not make it non-ingestible. There are several known examples of items that are not intended to be ingested but still end up being ingested by a motivated human, oftentimes children, and at other times thrill-seeking adults. Applicants argue that "Raylman '880 teaches away from using an ingestible device, since his device is adapted for replacing of the probe tips by the medical practitioner during the course of the procedure" (page 7, fifth paragraph, Remarks). Examiner contends that the fact that Raylman's probes are modular does not teach away from anything unless the claims recite the idea of the probe not being modular, in which they

do not. As explained above, Raylman's probe is still considered "ingestible". Applicants are advised to amend or embellish on the "ingestible" feature of the probe such that their intended idea is properly expressed.

Applicants argue that Raylman '880 fails to teach a "sensor adapted to determine the location and orientation of the ingestible device in the gastrointestinal tract" (page 8, paragraphs 3-7). Examiner notes that this limitation is taught. The fact that Raylman's probes can have a long flexible tube connecting the probe tip to the probe body used to help in the orientation of the detector at the tip would in an of itself be a characteristic of the probe that allows the operator to 'sense' the direction of the probe. If the operator were conducting a procedure using Raylman's probe without being able to sense the position of the probe, then it would be impossible to ever reach the area that needs to be imaged. The fact that the operator knows to used a curved or straight probe to locate an area with the tip is sufficient to meet a limitation of "determining the location and orientation of the ingestible device". The "sensor", whether it be the operator, his hand, or the shape of the probe, would be inherently present given the fact that the operator has a good enough idea of where the probe is to locate an area of interest. Again, Applicants seem to be inferring a narrower interpretation than what is allowed by the claim language. If Applicants are trying to claim an optical or magnetic tracking system, then Applicants should explicitly claim it. If Applicants are trying to claim a display showing a 3D coordinate point indicating the location of the probe and a mathematical orientation vector, then Applicants should explicitly claim it. However, the claim language as it stands does not warrant a narrower interpretation.

***Conclusion***

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELMER CHAO whose telephone number is (571)272-0674. The examiner can normally be reached on Mon-Thurs 11am-9pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ruth S. Smith/
Primary Examiner, Art Unit 3737

/E. C./
Examiner, Art Unit 3737